March 13, 2013

APPROVAL SHEET

Title of Dissertation: "The SMILE Program: Does Timing and Dosing of Nurse Home Visits Matter in Reducing Adverse Birth Outcomes for African American Women?"

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03/13/2013

THESIS AND ABSTRACT APPROVED:

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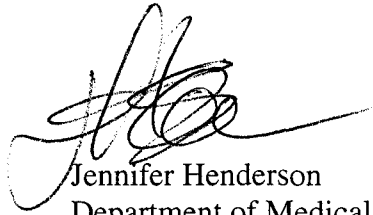DEPARTMENT OF MEDICAL & CLINICAL PSYCHOLOGY
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4 March 2013

The SMILE Program: Does Timing and Dosing of Nurse Home Visits Matter in Reducing Adverse Birth Outcomes for African American Women?

A Thesis submitted to the faculty of the
Department of Medical and Clinical Psychology Graduate Program
of the Uniformed Services University of the Health Sciences
in partial fulfillment of the requirements for the degree of
Doctor of Philosophy

By
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13 November 2012

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Abstract

Statement of Problem. Program evaluation is vital to examining the effectiveness of existing public health programs in the area of infant mortality. Despite considerable progress in reducing infant mortality in the United States, African Americans experience nearly twice the rate of infant mortality than their Caucasian counterparts for the past decade. Low birth weight (LBW) and preterm delivery are the two leading causes of infant mortality and this disparity.

Methods. Participants were 384 African American/Black women with singleton pregnancies enrolled in the Start More Infants Living Equally Healthy (SMILE) program, a program targeting high-risk African American/Black women in Montgomery County, MD. Health outcomes at birth (i.e., LBW, prematurity, and birth anomalies) were examined in relation to the week of entry, trimester of enrollment, and frequency of nurse home visits.

Results. Infants within the program experienced few adverse birth outcomes: 76% had no birth anomaly, while only 3.4% were born at a LBW and 8.3% were born prematurely. Women received an average of 2.08 (SD=1.66) home visits. No statistically significant association between the enrollment trimester or in the frequency of their home visits and the outcome variables were observed. However, analyses by week of program entry found earlier enrollment, up to 21 gestational weeks, offered a protective influence against preterm delivery ($p=.006$).

Conclusions. Women enrolled in this NHV program were at-risk for adverse birth outcomes and yet experienced fewer adverse outcomes than would be anticipated despite receiving fewer than expected visits. Earlier enrollment increased the protective influence of NHV against premature birth. Results of this program evaluation suggest antepartum NHV program may be protective against infant mortality in this population.

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Introduction

Infant Mortality

National trends. Infant mortality, defined as the death of an infant in the first year of life, is considered one of the most sensitive indicators of the overall health of a nation, the ability of citizens to access quality health care, and general socioeconomic conditions (Alexander, Wingate, Bader, & Kogan, 2008). Infant mortality is not a concern relegated to less developed nations. It remains salient in the United States (U.S.). In 1960, the U.S. ranked 12th in the world with a relatively low infant mortality rate (IMR), defined as number of infants dying within their first year of life per 1,000 live births; by 2004, however, the U.S. fell to 29th in the world (MacDorman & Mathews, 2009). The Healthy People 2020 target for IMR is 6.0 infant deaths per 1,000 live births. In order to achieve and maintain this rate, the subpopulations with greater IMR must be targeted.

Health disparities. In the U.S., the burden of infant mortality remains highest among racial and ethnic minorities. For the past decade, it has been highest among non-Hispanic African Americans, as depicted in Figure 2. The African American to Caucasian IMR ratio has increased from 2.0 in 1979 to 2.4 in 2005 (Fry-Johnson, Levine, Rowley, Agboto, & Rust, 2010). More specifically, in 2006 the IMR among Caucasians was 5.6, compared to nearly twice that for African Americans (12.9). Moreover, at no point since 1983 has the disparity between Caucasians and African American infant or neonatal mortality—defined as infant death occurring within the first 28 days of life—dipped below double the risk for African Americans (NCHS, 2011). Improvements in the U.S. IMR have largely been attributable to medical advances in prenatal care and perinatology, as well as to improvements in antepartum and

perinatal care for high risk infants (Headley, 2004). However, not all Americans have equally

benefitted from these advances and improvements.

The health disparity between Caucasian and African American infant mortality has been

largely attributable to the wide gap in low or very low birth weight (LBW/VLBW) and preterm

deliveries among African Americans (Ashton, 2006; CDC, 1999, 2000, 2002). Low birth weight

is defined as weight at birth of less than 2,500 grams (5.5 pounds), while very low birth weight is

defined as a birth weight of less than 1,500 grams (3.3 pounds; CDC, 2002). Premature birth is

defined as a gestational age at birth of less than 37 weeks (WHO, 1992). Although Healthy

People 2020 advocates reducing the incidence of LBW to 7.8% and the percentage of preterm

births to 11.4%, we are far from achieving these goals for all groups of Americans. For example,

in 2010 the percentage of African American babies born with LBW was nearly twice that of

Caucasians (13.5% versus 7.1%). Similarly, the percentage of preterm births among Caucasians

was 10.8%, compared to 17.2% among African Americans (NVSR, 2011).

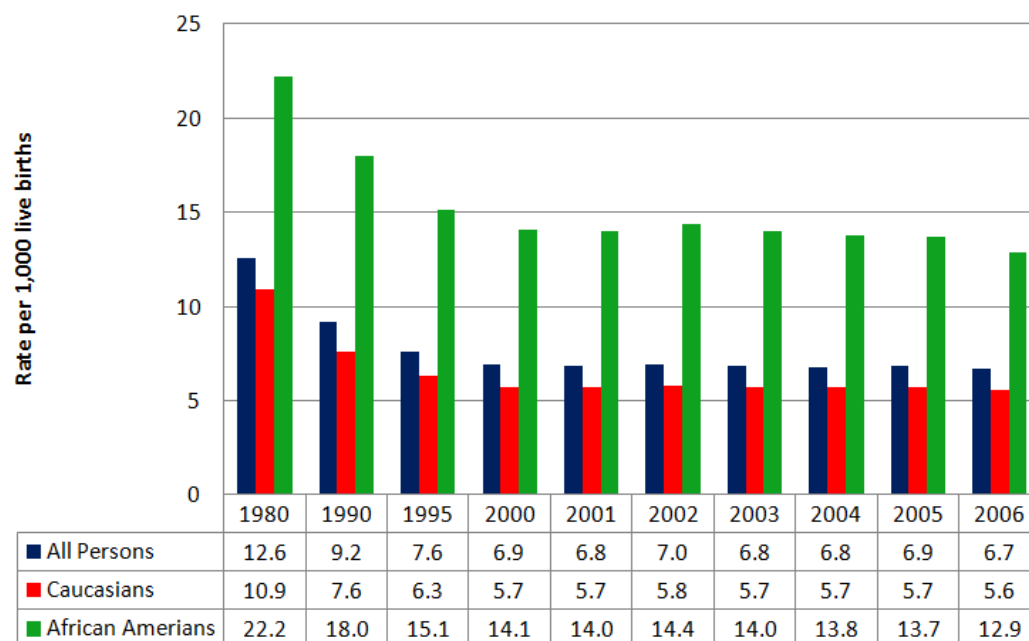|	1980	1990	1995	2000	2001	2002	2003	2004	2005	2006
All Persons	12.6	9.2	7.6	6.9	6.8	7.0	6.8	6.8	6.9	6.7
Caucasians	10.9	7.6	6.3	5.7	5.7	5.8	5.7	5.7	5.7	5.6
African Amerians	22.2	18.0	15.1	14.1	14.0	14.4	14.0	13.8	13.7	12.9

Figure 1. U.S. Infant Mortality Rate by Race (1980-2006). This figure depicts data from the National Vital Statistics System (2011) regarding the change in IMR for Caucasians and non-Hispanic African Americans in the United States.

These trends are particularly disturbing given that gestational age and birth weight may be the most important contributors to an infant's subsequent health and survival. Premature infants are at greater risk of death, and this too reflects a health disparity as preterm-related IMR for non-Hispanic African Americans are 3.4 times higher than for non-Hispanic Caucasians (MacDorman & Mathews, 2010). Birth weight is similarly an important indicator for both short- and long-term health. Infant mortality rates are highest for VLBW infants and significantly decrease as birth weight increases; according to data from the National Vital Statistics Report, the IMR for VLBW infants was 240.4 which corresponds to more than 100 times the IMR for infants born at a healthy weight ($\geq$ 2,500 grams; Mathews & MacDorman, 2010).

Moreover, those infants surviving their preterm birth and/or low birth weight are more likely to be placed in foster care (Lee et al., 2009), maltreated during childhood (Lee et al., 2009), and experience more health problems throughout their life span. These problems include higher rates of impaired growth, ADHD, cognitive and neurodevelopmental deficits, psychiatric illness (particularly during adolescence), hypertension, diabetes, cardiovascular disease, and both short- and long-term disability (Behrman, 2007; Conley, 2000; Raikkonen et al., 2007).

Relative costs. Recent reporting on national trends in infant mortality equates the American IMR to nearly 30,000 infants dying within their first year of life. This number, however, cannot account for the true cost of infant mortality. The true cost includes the greater impact on parents, families, neighborhoods, communities, and society. Parents, and potentially the wider family as a whole, are subjected to potentially uncompensated loss of workdays and income; profound interruptions to familial routines or obligations; incur additional travel, medical, and childcare costs; and incalculable personal stress and emotional turmoil. At the widest circle of those impacted by high risk infants (e.g., LBW and those born prematurely) and

infant mortality, national expenditures caring for these infants are in excess of tens of millions of dollars (Headley, 2004). Finally, it cannot be over-emphasized that this does not capture the disturbing additional burden infant mortality has for racial and ethnic minorities within the United States.

Reducing Infant Mortality Health Disparities

      Possible risk factors. Although various factors have been suggested to contribute to the disproportionate IMR, none has been demonstrated to be the "smoking gun." For example, certain prenatal health behaviors such as smoking or receiving adequate prenatal care are widely associated with overall fetal health. However, while smokers across all races/ethnicities generally have worse birth outcomes than non-smokers, African American non-smokers still have a higher prevalence of poor birth outcomes than Caucasian or Hispanic women who smoked.. Likewise, while prenatal care is beneficial for all women, it too has not been conclusively linked to the preponderance of adverse birth outcomes experienced by African Americans. Even African Americans beginning prenatal care in their first trimester and continuing to receive it throughout their pregnancies still have higher IMRs than Caucasians who did not receive the same level of prenatal care (Alio et al., 2010; Byrd, Katcher, Peppard, Durkin, & Remington, 2007; Healy et al., 2006; Rowley, 1995).

      It has also been suggested that maternal socioeconomic status (SES) can contribute to higher IMR and it has been generally shown that as maternal SES increases, IMRs decrease. However, even affluent African Americans and those with higher educational achievement experience higher rates of infant mortality than Caucasians (Foster, Wu, Bracken, Semenya, & Thomas, 2000; Headley, 2004). Some have also suggested that community and cultural factors contribute to the higher IMR experienced by African Americans (Alio et al., 2010; Bell,

Zimmerman, Almgren, Mayer, & Huebner, 2006; Bell, Zimmerman, Mayer, Almgren, & Huebner, 2007; Gennaro, 2005; Goza, Stockwell, & Balistreri, 2007; Headley, 2004; Kramer, Cooper, Drews-Botsch, Waller, & Hogue, 2010), but research on these factors has been (Alexander et al., 2008; Lobel, Dunkel-Schetter, & Scrimshaw, 1992; Spong, Iams, Goldenberg, Hauck, & Willinger, 2011).

Understandably then, agencies such as the World Health Organization and policy initiatives like Healthy People 2020 now acknowledge that health is too complex a phenomenon to not be considered within the broader social, cultural, and economic environments in which people live, work, and play (Evans, Barer, & Marmor, 1994; Marmot, 2005; Solar & Irwin, 2010). Thus, the emergent trend is to examine how and to what extent the various psychosocial, economic and political, and biological pathways of social determinants of health synergistically influence health, both positively and adversely (Chin et al., 2012; Chin, Walters, Cook, & Huang, 2007; Colditz & Wei, 2012; Cummins, Stafford, Macintyre, Marmot, & Ellaway, 2005; Ferreira-Pinto LM, 2012; Ferrie, Martikainen, Shipley, & Marmot, 2005; Freudenberg, Klitzman, & Saegert, 2009; Gerend & Pai, 2008; Knutson, 2012; Kumari, Marmot, Rumley, & Lowe, 2005; Solar & Irwin, 2010; Vona-Davis & Rose, 2009).

Nurse home visitation (NHV) programs. Given the emergence of the social determinants of health framework, one approach to improve health for those that have historically been disenfranchised is to increase utilization of community-based health interventions (Austin & Harris, 2011; DeBate, Plescia, Joyner, & Spann, 2004; Dodani & Fields, 2010; Gehlert & Coleman, 2010; Kanaya et al., 2012; Kang-Yi & Gellis, 2010). An approach to reduce and eliminate infant mortality has been that of home visitation (*cf*. Olds, Henderson et al. 1986; Kitzman, Olds et al. 2000; Nguyen, Carson et al. 2003; Dawley and Beam 2005). Home

visitation has been loosely defined as a targeted health care service delivered within a family's

home for the express purpose of providing health information and social support to childbearing

women and their children (Ammerman et al., 2006; Daro, 2006; Gomby, 2000; Witgert, Giles, &

Richardson, 2012)

NHV programs are widespread across the United States. Examples of such programs

include the Start More Infants Living Equally Healthy (SMILE) initiative; Nurse-Family

Partnership; Head Start programs; Healthy Families America; and the Resources, Education, and

Care in the Home (REACH) program (Stoltzfus & Lynch, 2009). Despite the differences among

these agencies in goals, nature of providers, and/or activities, they share common elements:

structured services (e.g., referrals, education), care provided by a nurse or other trained provider,

conducted in home settings, and designed to provide social support while influencing the

mothers' health knowledge, beliefs, and practices (Behrman, 2007; Halpern, 2000; Stoltzfus &

Lynch, 2009; Wasik & Bryant, 2000; Witgert et al., 2012).

Unfortunately, there is not definitive evidence that NHV programs are advantageous.

Many studies find these programs to be an effective, culturally sensitive service-delivery method

for improving birth outcomes among high risk women (e.g., adolescents, African Americans,

Latina Americans, substance abusers) who may lack strong social support networks, have

reduced access to health care (e.g., lack of insurance, transportation), or have insufficient

prenatal education (Carabin et al., 2005; Donovan et al., 2007; Issel, Forrestal, Slaughter,

Wiencrot, & Handler, 2011; Lee et al., 2009; Norr et al., 2003; Olds et al., 2002; Olds et al.,

2004; Wells et al., 2008). However, other studies evaluating the effectiveness of home visitation

programs have found few if any measurable benefits while others lacked formal evaluation of

maternal-infant outcomes (Brooten et al., 2001; Donovan et al., 2007; Hodnett, Fredericks, &

Weston, 2010; Margolis et al., 2001). Thus, the available research on NHV programs is inconclusive.

Before definitive statements about the efficacy or effectiveness of NHV programs can be made, a number of methodologic concerns must be addressed. There needs to be an agreed upon set of predictors (e.g., frequency of visits, enrollment timing, social support, stress) and outcomes (e.g., birth weight, gestational age, infant health, achievement of developmental milestones) used across studies. It has been previously noted that these inconsistencies may be due to methodological choices (Issel et al., 2011). Results may vary due to differing program protocols, nature of the specific intervention, targeted population demographics, clinical characteristics of the various samples, and geographic variations. In one sense, comparisons across these programs are like comparing apples to oranges, or tangerines to oranges. Program characteristics are too diverse, targeted populations are too dissimilar, and the actual quality of the various studies may be too disparate to make a valid or definitive assessment as to whether antenatal home visitation programs are universally effective or not in promoting positive maternal and infant health outcomes. Clearly, there exists a pressing need to collectively identify and use consensus-driven predictors and outcomes to effectively study NHV programs. With these data available, we would be able to more accurately assess the effectiveness of specific programs within specific populations. Such effectiveness trials could follow once a particular program's efficacy had been determined.

Present Study

  Context. Historically, Maryland's IMR has been above the national average (DHMH, 2011a). While the previous year witnessed a notable decline in the IMR for the state overall, startling health disparities remain. Since at least 2001, the rate of African American infant

mortality consistently has been two to three times as high as Caucasians (DHMH, 2011). Further analysis of this trend shows that the three leading causes of infant death in Maryland are complications related to premature deliveries and LBW, congenital abnormalities, and sudden infant death syndrome (SIDS). Here too, the health disparities between Caucasians and African Americans are quite notable. African American infants were five times more likely to die in 2010 as a result of complications of the placenta, cord and membrane; four times more likely to die due to SIDS or LBW; and three times more likely to die due to maternal pregnancy complications as Caucasians (DHMH, 2011a).

Consequently, the state has invested in NHV programs to supplement traditional prenatal care services provided by hospitals and clinics. These programs provided focused, tailored, and culturally-relevant services for expectant parents and young children by promoting attachment, optimal development, and general health and wellbeing. Five nationally recognized NHV programs used throughout the state include the Nurse-Family Partnership, Healthy Families America, Parents as Teachers, Home Instruction for Parents of Preschool Youngsters (HIPPY), and Early Head Start. Locally managed programs include Baltimore's Healthy Start program and Montgomery County's Start More Infants Living Equally Healthy (SMILE) initiative (ACY, 2009; DHMH, 2011b).

The SMILE program. In Montgomery County, the African American Health Program (AAHP) offers a myriad of health programs for African Americans to include free nurse home visitation for pregnant women, under the auspices of the Montgomery County Department of Health and Human Services (DHHS). Since 2003, AAHP has provided a multi-component intervention to pregnant African American women residing in Montgomery County, Maryland in the form of the SMILE initiative.

Specifically, the SMILE program offers education, community referrals, and social support to this at-risk population. The education component is multifaceted, targeting specific issues during both the antepartum period (e.g., nutrition, signs of preterm labor) and in the first year of the infant's life (e.g., importance of self-care, "baby blues," infant stimulation). Referrals are offered if the nurse manager believes counseling is warranted for depression, sexual abuse, stress or anxiety, as well as for other community services (e.g., breast pumps, food, cribs, car seats). The nurse managers do not provide medical care, instead they work cooperatively with the mothers' primary physician. Three full-time nurse managers are employed with a client to nurse ratio of 50:1 (Wells et al., 2008).

Women can enter the program either during their pregnancy or after delivery, although since 2008 the program generally only allows postpartum enrollees if they have a history of high-risk pregnancies. While those entering the program during the antepartum period are encouraged to receive a minimum of once a month home visitations, their preferences and needs ultimately determine the frequency of the visits. Women are discharged from the SMILE program once their child has reached one year of age. Eligibility requirements for the SMILE program are quite liberal, requiring only that the woman be African American or of African descent and be a resident of Montgomery County. There are no age, income, educational, or insurance requirements (AAHP, 2012).

Since its inception in 2003, there has been one study evaluating the effectiveness of this NHV program in reducing adverse birth (Wells et al., 2008). The principal objective of the study was to compare the incidence of poor birth outcomes in women receiving nurse home visitation with those who did not. Of the 109 women included in the study, those receiving nurse manager visits had fewer preterm deliveries and low birth weight infants than those who were not enrolled

in the program although NHV was only statistically associated with a reduction in preterm births. Consequently, home visitation appeared to be a protective factor against preterm delivery when accounting for differences in level of prenatal care, previous gravida, and negative life events (Wells et al., 2008).

      Program evaluation. The present study represents a follow on program evaluation for the SMILE Program, and improves upon the previous study by having a much larger sample size. It is important to note that program evaluation is substantively different from formal research, even if both may share some of the same methodologies. Formal research typically requires a control group and rigorous control for the effects of extraneous variables, and is useful for informing the wider scientific community about the effectiveness of a particular treatment protocol. In contrast, program evaluations typically lack a control group, cannot as rigorously control for extraneous variables, and the benefits of program evaluation are directly tied to the program under investigation and its stakeholders, and are thus usually intended to inform and promote community capacity (Baker, Davis, et al., 2000; DCoE, 2012).

      The proposed program evaluation is an outcome evaluation and involved a multi-phase collaborative dialogue and investigation between the USU research team and the AAHP stakeholders, specifically the nurse case managers and past/present program directors of the SMILE program. The first phase entailed stakeholder analysis, which was conducted utilizing qualitative interviews with past and present program directors. Phase 2 was performed using a quantitative retrospective, longitudinal study evaluating how effectively the program reduced the prevalence of LBW and preterm deliveries in the women participating in the SMILE program. Finally, the third phase involved a qualitative review of the outcome evaluation with AAHP program staff to ensure the study's results were properly framed within the context of the

community and that collaborative investment was gained in applying these results to generate the best possible intervention for the women served by participating in the SMILE program.

   Research aim and hypotheses. Inconclusive evidence on the effectiveness of NHV programs necessitates consistency in defining program predictors and outcomes including enrollment timing and dosing. No study to date has examined whether timing of maternal enrollment in a home visitation program affects birth outcomes. The present study sought to extend the original Wells and colleagues (2008) study. The original study could not be replicated due to programmatic changes in enrollment criteria instituted by AAHP in 2008. Specifically, postpartum enrollment has been restricted to high-risk mothers since 2008 creating a confound between antepartum and postpartum enrollment comparisons. Accordingly, the purpose of the present study was to conduct a program evaluation focusing on the major adverse birth outcomes. This work extends the original Wells and colleagues (2008) study by examining whether differences in health outcomes at birth (gestational age, birth weight, and birth anomalies) varied based on the trimester or week of enrollment. Since enrollment timing likely affects birth outcomes, it was hypothesized that those enrolling later in pregnancy would have more adverse birth outcomes. Additionally, it was hypothesized that frequency of home visits (i.e., dosing) would also affect birth outcomes, such that those with few home visits would be at greater risk of experiencing an adverse birth outcome. In addition to providing evidence as to the effectiveness of the SMILE program, the findings of this study help fill research gaps by providing much needed information about whether the effectiveness of antepartum home visitations varies due to enrollment timing and/or dosing of such interventions. Filling this research gap is vital, both for public health policy initiatives as well as to comply with the

Affordable Care Act (P.L. 111-148) mandate to document outcomes of home visitation programs (DHMH, 2011b).

Methods

Study Design

This retrospective, longitudinal program evaluation study evaluated the impact of NHV on birth outcomes in African American/Black women in Montgomery County, Maryland. Clinical and demographic data on women enrolled in the SMILE program were extracted from a database maintained by the African American Health Program. The project was approved by the Uniformed Services University of Health Science institutional review board.

Participants

Participants were chosen from the 729 non-Hispanic Caribbean, African American, or African-descent women enrolled in the SMILE program during either the antepartum or postpartum periods between January 2003 and December 2011. The present study focused exclusively on women enrolling in the antepartum period.

The majority of antepartum enrollees entered into the SMILE program during their third trimester (n=225, 59%). The typical participant was 27 years old (SD=7.25), born in the United States (63%), experienced paternal involvement in their pregnancy (59%), and had less than a college education (52%). Fifty-seven percent were unemployed and most utilized medical assistance (70%). The average number of gravida was 2.39 (SD=1.872); approximately 4% had no prior pregnancies. More than 14% had three or more children living at home at the time of their present pregnancy.

Inclusion criteria. The study sample of 384 women was selected from the 729 women participating in the SMILE program based on the following inclusion criteria: 1) singleton

pregnancy, 2) documented antepartum enrollment, and 3) documented infant weight and

gestational age at birth.

Multiparous pregnancies were

excluded from analysis due to

the increased likelihood of

pregnancy complications

which could result in

premature delivery and/or

LBW (Cunningham et al., 2005;

Lopriore et al., 2009; Nicholson

Figure 2. Study Design.

et al., 2009). Altogether, as depicted in Figure 2, 384 women were excluded with 177 of these

excluded due to their postpartum enrollment.

Measures

      Independent variables. Group assignment was the primary independent variable.

Groups were determined based on the specific trimester the women had enrolled in the SMILE

program. Gestational week of program entry was also used as a predictor variable along with

dosing (number of home visits).

      Dependent variables. The dependent variables were birth outcomes, indexed by birth

weight, gestational age at birth, and presence of birth anomalies as defined below.

      Low birth weight (LBW). The primary outcome measure was birth weight. Birth weight

was dichotomized as either low birth weight (< 2,500 grams or 5 lbs 5 oz) or normal birth weight

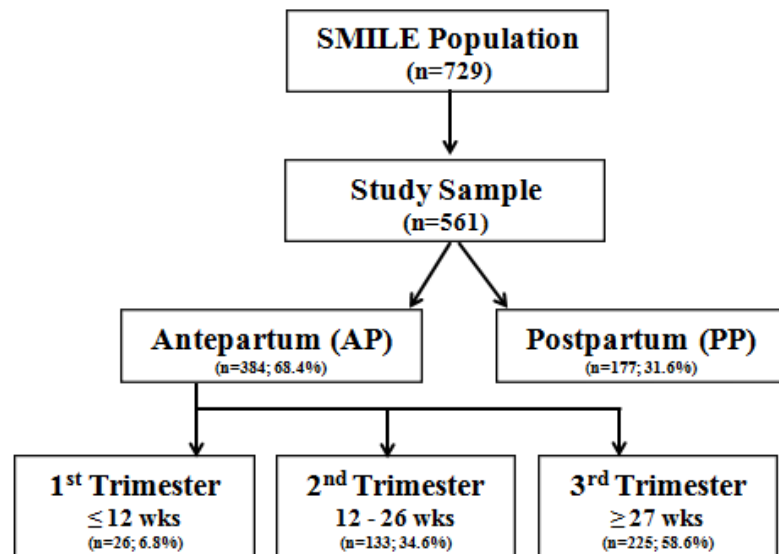(≥ 2,500 grams). Very low birth weight infants (< 1,500 grams or 3 lbs 3 oz) were also included

within this classification (Behrman & Butler, 2007). For analytical purposes, LBW was

dichotomized as either presence or absence of LBW.

Gestational age. Gestational age at birth was dichotomized as either premature (occurring

at less than 37 weeks) or term (≥ 37 weeks) based on the first day of the last menstrual period

(Behrman & Butler, 2007). For analytical purposes, gestational age was dichotomized as either

presence or absence of premature birth.

Birth anomalies. Birth anomalies was broadly defined as congenital defects, jaundice,

admittance to the neonatal intensive care unit (NICU), physiological issues (e.g., cardiac, renal,

gastrointestinal problems, etc.), meconium stained aspiration, prenatal drug exposure, anemia,

sickle cell trait, or identification of any other adverse health condition to include premature birth

and LBW. Birth anomalies were dichotomized as the presence or absence of 3 or more birth

anomalies. This cutoff value for characterizing the presence of birth anomalies was chosen

because the average number of birth anomalies, if any, was two.

Analytic Plan

Statistical analyses were performed using SPSS v19.0. Demographic and clinical

characteristics of antepartum women based on the trimester of enrollment into the SMILE

program were compared. Statistical significance was set at an alpha level of 0.05, two-tailed. In

this investigation, the principal source for error was the presence of missing data. Unless missing

data pertained to the principal independent or outcome variables, client data was included in the

analysis despite the presence of missing data.

This study utilized descriptive statistics. Logistic regression was used to examine the

relationship between gestational week of entry into the SMILE program and birth outcomes.

Logistic regression was an appropriate measure for this analysis because the outcome variables

(i.e., birth outcomes) were categorical in nature and the independent variable was ordinal in nature. Pearson's chi-square and Fisher's exact tests were used to examine the research question of whether a statistically significant relationship exists between the independent variables (i.e., trimester, dosing) and birth outcomes. Fisher's exact test and chi-square tests were appropriate statistical measures given that the purpose of the analyses was to test the relationship between two nominal level variables.

Assumptions of chi square tests necessitate that the data be random samples of multinomial mutually exclusive distribution and the expected frequencies should not be too small and typically not less than five. If the expected cell frequencies were less than five and the results were significant ($p<.05$), the cell frequency was annotated. It should be noted, however, that chi-square tests are sufficiently robust to withstand the occurrence of small expected frequencies (Bradley at al., 1979; Camilli & Hopkins, 1979; Howell, 2010) and ultimately produce few Type I errors as long as the total sample size is sufficient (n ≥8; Camilli & Hopkins, 1979). Where appropriate, Fisher's exact test was used to confirm significance if a significant result was found utilizing a chi-square test. Using the Fisher's exact test reduced the likelihood of any errors arising from this approximation of significance.

Results

Demographics

Table 1 (*see* Appendix A) presents the sample characteristics by trimester the women enrolled in the SMILE program; no statistically significant demographic differences exist among these three groups of women. These women averaged 2.08 home visits (SD=1.66).

Outcomes

Of the infants born to the 384 participants included in this study, 13 were born at a LBW (3.4%), 1 was VLBW (0.3%), 32 were born prematurely (8.3%), and 293 were born without any documented birth anomaly (76%) as shown in Figure 3.

Primary analyses. Because of the dichotomous and categorical nature of the outcome variables, Pearson's chi-square test and Fisher's exact test were used to determine whether a statistically significant relationship existed between specific enrollment trimester, dosing, and birth outcomes.

	1st Trimester (n=26)	2nd Trimester (n=133)	3rd Trimester (n=225)
IVs:	Avg. HV: 4 (SD=2.6)	Avg. HV: 2.56 (SD=2.0)	Avg. HV: 1.57 (SD=0.93)
DVs:	LBW: 0 (0%) PD: 2 (6%) ≥3 BA: 0 (0%)	LBW: 3 (23%) PD: 15 (47%) ≥3 BA: 7 (58%)	LBW: 10 (77%) PD: 15 (47%) ≥3 BA: 5 (42%)

$p > .08$

Figure 3. Birth Outcomes among Antepartum Enrollees. Our results suggest no significant association (p >.08) between the trimester of enrollment and birth outcomes. LBW: Low birth weight. PD: Premature delivery. BA: Birth anomalies.

LBW. Overall, there were few LBW infants (n=13; 3.4%). While it appeared that those enrolling later in their pregnancies were more likely to have a LBW infant with 10 of the 13 LBW infants (76.9%) born from women enrolling in their third trimester, this trend, however, was not statistically significant (χ^2= 2.202, df= 2, p=.333).

Prematurity. Similarly, of the 32 infants born prematurely, 93.8% were born to mothers enrolling in the second and third trimesters (46.9% for each). However, the difference by trimester was not statistically significant (χ^2= 2.342, df= 2, p=.310).

Birth anomalies. Ninety-one infants (23.7%) experienced one or more birth anomalies; 12 of these infants experienced three or more birth anomalies (3.1%). There was no significant

relationship between trimester of enrollment and presence of three or more birth anomalies ($\chi^2=$ 9.154, df= 6, p=.165).

Dosing. Additionally, no significant relationship was observed between the frequency of the nurse home visits and having a LBW infant ($\chi^2=$ 5.084, df= 9, p=.827), delivering prematurely ($\chi^2=$ 8.230, df= 9, p=.511), or having an infant with three or more birth anomalies ($\chi^2=$ 2.889, df= 9, p=.969).

Secondary analyses. Additional analyses were conducted to determine if a relationship existed between gestational week of enrollment and prematurity, type of birth anomaly and enrollment timing, and health history and birth outcomes.

Prematurity. There was a significant relationship between week of program entry and gestational age ($\chi^2=$ 7.867, df= 1, p=.006, Cramer's ψ= .143, OR=.361). Enrollment timing was dichotomized as program entry $\leq$ to 21 gestational weeks versus entry at 22 gestational weeks or later. Specifically, earlier enrollment was a protective factor. Just over 53% of the premature infants were born to women enrolling at $\geq$ 22 gestational weeks. Overall, more than 65% of premature births occurred to those infants' whose mothers enrolled at $\geq$ 20 gestational weeks ($\chi^2=$ 4.467, df= 1, p=.035, Cramer's ψ= .108, OR=.441).

Type of birth anomaly. A chi-square test revealed a significant association between specific kinds of birth anomalies and enrollment timing. Specifically, there was a significant relationship between the trimester enrolled within and an infant being born jaundiced (χ^2=6.374, df=2, p=.041, Cramer's ψ=.129)[†]; more than 60% of the infants born jaundiced were seen in those whose mothers enrolled in the third trimester.

Obstetrical history. Health history was examined as a potential confound to the study's results. Pearson's chi-square tests were used to examine whether a woman's obstetric history of

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[†] One cell (16.7%) had an expected count less than five; Fisher's exact test was not available for use in this analysis.

prenatal health conditions contributed to either a LBW or premature birth infant. No health

conditions predicted birth outcomes: yeast infections (LBW: χ^2= .458, df= 1, p=.422; Premature:

χ^2=.469, df= 1, p=.370), substance usage (LBW: χ^2= .070, df= 1, p=.933; Premature: χ^2=.183,

df= 1, p=.840), preeclampsia (LBW: χ^2= .034, df= 1, p=.967; Premature: χ^2=.087, df= 1,

p=.920), placenta previa (LBW: χ^2= .173, df= 1, p=.845; Premature: χ^2=.439, df= 1, p=.659),

hypertension (LBW: χ^2= .103, df= 1, p=.904; Premature: χ^2=.262, df= 1, p=.779), bacterial

vaginosis (LBW: χ^2= .138, df= 1, p=.874; Premature: χ^2=.350, df= 1, p=.716), uterine

abnormalities (LBW: χ^2= .069, df= 1, p=.935; Premature: χ^2=.174, df= 1, p=.847), and

gestational diabetes (LBW: χ^2= .351, df= 1, p=.712; Premature: χ^2=.058, df= 1, p=.569). These

prenatal health complications were not significantly associated with the primary outcome

variables in this study.

Discussion

Background

Only one previous study (Wells et al., 2008) examined the effectiveness of the SMILE

program in reducing factors contributing to African American infant mortality. In that study, the

authors found some evidence suggesting that home visitations were protective against preterm

deliveries. The present study extends the previous program evaluation by evaluating whether

enrollment timing and dosage of home visits are associated with birth outcomes.

Findings

No statistically significant association was observed between birth outcomes and specific

trimester of enrollment or frequency of home visits. However, week of enrollment was

associated with preterm deliveries. Specifically, enrollment timing up to 22 gestational weeks in

a NHV program is negatively associated with premature birth.

Women enrolled in SMILE represent a high-risk group of women, the majority of whom have low incomes, are unemployed, utilize medical assistance, and have an increased likelihood of racially-based health disparities. Despite being at-risk for experiencing an adverse birth outcome, these women were less likely to have a LBW infant or deliver prematurely. When looking at these results within the context of the higher percentage of LBW and premature births among African Americans nationally, within the State of Maryland, and in Montgomery County our study suggests that NHV may offer a promising means to proffer a protective influence on pregnant African American women.

Implications

These results are significant for several reasons. While the hypotheses were not confirmed, African American/Black women participating in the SMILE program were less likely to have a preterm and/or LBW infant than expected by state or national data. The importance of this finding cannot be underemphasized. Historically, the state of Maryland has had some of the highest infant mortality rates in the nation and has historically been higher than the national average, facts which prompted Governor O'Malley's administration to declare reducing infant mortality as one of the 15 strategic goals to improve the quality of life for Maryland residents (DHMH, 2011a). According to the Maryland Department of Health and Mental Hygiene, this higher State rate of infant mortality is primarily caused by the higher proportion of African Americans residing in the state, a racial group that generally experiences higher infant mortality rates than their Caucasian counterparts. The rates of infant mortality for African Americans residing in Maryland have been historically higher than those of the national average for many years, and the leading contributors to these heightened rates are disorders associated with LBW and premature birth (DHMH, 2011a).

The state has invested in local and state-wide programs aimed at reducing African American infant mortality such as the Baltimore based B'More for Healthy Babies and the Montgomery County based SMILE program. The former program worked towards improving home visitation programs in the Baltimore area in 2011, while the latter initiative has provided NHV since 2003. The earlier Wells et al. (2008) evaluation and the present evaluation suggest antepartum NHV does protect against two of the leading causes of infant mortality. This is consistent with other research findings in which home visitation programs are seen to positively affect birth weight and gestational age (Brooten et al., 2001; Carabin et al., 2005; Koniak-Griffin et al., 2003; Lee et al., 2009; Nguyen, Carson, Parris, & Place, 2003; Ricketts, Murray, & Schwalberg, 2005; Wells et al., 2008). Further, while the present study did not generally find a significant relationship between frequency of these home visits or enrollment timing and adverse birth outcomes, it did suggest that earlier enrollment (prior to 22 gestational weeks) increased the protective influence of NHV against premature birth. This has significant clinical implications as it demonstrates the importance of early outreach to African American women to truly maximize the effectiveness of such community-based services.

Limitations

The proposed study is one of program evaluation. This means that some of the methodologies common to formal research are not applicable. For instance, as one might expect in community-based participatory research or other public health initiatives, randomization is not an option given that health service providers must offer services to those who qualify to receive said services. Similarly, there is no control group (e.g., Hispanic adolescents also at risk of adverse birth outcomes) to evaluate whether our results are generalizable to all pregnant women and particularly those at greatest risk of experiencing an adverse birth outcome. Additionally,

there were few first trimester enrollees, which also may impact the quality of the quality of the

results. It is conceivable that with more first trimester enrollees, the study would have found

statistically significant associations between enrollment timing and birth outcomes. Ultimately,

these limitations so common to community-based participatory research may affect the validity

and generalizability of results.

Another potential limitation to this study is the absence of certain variables which may be

worth investigating. As robust as the SMILE program's client database is, the fact remains that

there are certain questions pertinent to clinical characteristics and outcomes that are not asked or

fully explored by the program and its staff. For instance, while the program monitors whether the

women have present or historical obstetrical complications, it does not query them about some of

the health behaviors they engage in (e.g., whether they are taking prenatal vitamins, eating

appropriately for their pregnancy nutritional needs, complying with their physician's

instructions) which could affect their birth outcomes. Certain conclusions can be made by

examining those factors known to affect birth outcomes, but it would be useful to assess more

thoroughly their pregnancy related knowledge and behaviors.

Finally, while the goal of the SMILE program is for the nurse home managers to engage

with the participating women at least once a month during the antepartum period, our analysis

reveals that such did not necessarily happen. Antepartum enrollees received an average of just

2.08 home visits and even those enrolling as early as the first trimester received an average of

just four home visits. Given some of the potential limitations of research being conducted in a

public health initiative, it is possible that data regarding frequency of home visits may be

inaccurate. This inaccuracy may stem from incomplete data entry and/or technical problems with

the database; it is also conceivable that participants moved or were temporarily unable to be

contacted for various reasons during the antepartum period. Ultimately, this may well impact the validity of the study's finding that frequency of home visits was not associated with birth outcomes.

Future Research

This study filled a research gap by examining whether enrollment timing and dosing of home visitations influenced birth outcomes in women participating in a NHV program. Future studies should identify which components of NHV programs contribute to reducing adverse birth outcomes such as LBW and premature birth. Individual program components of the SMILE initiative were not evaluated in the earlier Wells and colleagues study or in the present study. Additionally, information on client knowledge, attitudes, and behaviors are not collected by the nurse case managers. This should be assessed in future studies to determine the key mechanisms for multi-factorial programs such as the SMILE program. Finally, few if any studies have obtained program participants' evaluations to determine what they feel they gained from participating in a NHV program and to assess what program components or interventions they believed were particularly effective or missing.

Conclusion

In summary, this study is one of the few studies to evaluate the effectiveness of a NHV program designed to reduce the disproportionate burden of infant mortality experienced by African Americans. The results indicate that African American women enrolled in the SMILE program during the antepartum period were significantly less likely to experience adverse birth outcomes (e.g., low birth weight, premature birth, other birth anomalies). While specific trimester at time of enrollment was not significantly associated with birth outcomes, the results indicate a significant and clinically relevant association between enrollment up to 22 gestational

weeks and the risk of premature delivery. Specifically, women enrolling earlier in their

pregnancies had a far smaller likelihood of giving birth prematurely. The preliminary

effectiveness of this culturally-appropriate community based intervention suggests that NHV

may well benefit other communities and at-risk populations. With further investigation, we may

be able to say the SMILE program has effectively targeted and reduced infant mortality in

Montgomery County and may well serve as a useful template for other NHV programs to

similarly improve birth outcomes and reduce this disturbing health disparity.

Appendix A: *Table 1: Participant Characteristics by Trimester of Enrollment*

Demographic Variables	First Trimester n=26 (6.8%)	Second Trimester n=133 (34.6%)	Third Trimester n=225 (58.6%)
Age			
≤ 19yo:	2 (7.7%)	19 (14.3%)	37 (16.4%)
20-34yo:	19 (73.1)	89 (66.9)	143 (63.6)
≥ 35yo:	5 (19.2)	25 (18.8)	44 (19.6)
Nativity			
USA:	16 (61.5)	83 (62.4)	137 (60.9)
Foreign Born:	9 (34.6)	45 (33.8)	83 (36.9)
Relationship			
Coupled:	9 (34.6)	52 (39.1)	109 (48.4)
Uncoupled:	17 (65.4)	76 (57.1)	113 (50.2)
Education			
Less than HS:	3 (11.5)	25 (18.8)	27 (12.0)
HS/GED:	7 (26.9)	42 (31.6)	74 (32.9)
College:	15 (57.7)	54 (40.6)	115 (51.1)
Private Insurance			
Yes:	7 (26.9)	33 (24.8)	71 (31.6)
No:	13 (50.0)	77 (57.9)	98 (43.6)
Medical Assistance			
Yes:	14 (53.8)	82 (61.7)	133 (59.1)
No:	7 (26.9)	33 (24.8)	59 (26.2)
Employment			
Yes:	11 (42.3)	57 (42.9)	83 (36.9)
No:	3 (50.0%)	65 (48.9)	126 (56.0)
No. Prior Health Issues			
None:	18 (69.2)	89 (66.9)	180 (80.0)
1-2:	6 (23.1)	36 (27.1)	36 (16.0)
3+:	2 (7.7)	8 (6.0)	9 (4.0)
Presence Of 2+ Negative Life Events			
Yes:	9 (34.6)	48 (36.1)	83 (36.9)
No:	17 (65.4)	85 (63.9)	142 (63.1)

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